

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference A04P2002 P	FOR FURTHER ACTION	
International application No. PCT/SE2004/000698	International filing date (day/month/year) 06.05.2004	Priority date (day/month/year) 06.05.2004
International Patent Classification (IPC) or national classification and IPC INV. A61B5/02		
Applicant ST. JUDE MEDICAL AB		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ sent to the applicant and to the International Bureau a total of sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability


☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 02.12.2005	Date of completion of this report 05.07.2006
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Stern, M Telephone No. +49 89 2399-2239



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Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☐ the international application in the language in which it was filed
 - ☒ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☒ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-7 as published

Claims, Numbers

1-26 as published

Drawings, Sheets

1/4-4/4 as published

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify):*
 - ☐ any table(s) related to sequence listing *(specify):*
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing *(specify):*
 - ☐ any table(s) related to sequence listing *(specify):*

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 18-26

because:

- ☒ the said international application, or the said claims Nos. 18-26 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).
- ☒ no international search report has been established for the said claims Nos. 18-26
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☒ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	1-2
Inventive step (IS)	Yes: Claims	
	No: Claims	3-17
Industrial applicability (IA)	Yes: Claims	
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Regarding Section III:

1. The subject-matter of claims 18-26 comprises, inter alia, methods such as intracardiac electrograms (see, eg, page 2, lines 30-34 of the application) or other cardiac catheterization procedures for pressure and volume measurements (such as mentioned in document D3 cited below, under paragraph 2.2 thereof). Hence, claims 18-26 comprise, inter alia, surgical methods of treatment (Article 34(4)(a)(i) and Rule 67.1(iv) PCT).

Regarding Section V:

1. The following documents cited in the international search report will be addressed in the present report:

D1: WO-A-02/053 026
D2: WO-A-02/043 587
D3: Mandilov L. et al.: "Diastolic heart failure", Cardiovascular Research, Vol. 45, No 4, 2000, pages 813-825
2. The application does not fulfil the requirement of novelty and inventive step of Article 33(2), (3) PCT for the following reasons.
 - 2.1 Document D1 discloses an implantable apparatus which is suitable for detecting diastolic heart failure (cf page 1, lines 6-9) comprising means for determining the time length of a predetermined phase of diastole (page 7, lines 15-23). Also document D2 discloses such an implantable apparatus; cf in D2, page 4, lines 20-34; page 8, lines 12-14. Hence, the subject-matter of claim 1 lacks novelty.
 - 2.2 It is implicit from D1 and D2 that such time measurements are compared with normal limit values. Hence, the features of claim 2 are implicitly also disclosed in D1 and D2.
 - 2.3 Moreover, document D3 explicitly mentions the normal value range for isovolumic relaxation time tau at the bottom of page 817, so that the features of claims 2 and 6

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(SEPARATE SHEET)**

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would not involve an inventive step either. D3 also discloses the measurement of the time constant of relaxation, whereby the feature recited in claim 3 of determining the time length to the point where the blood flow velocity is zero is rendered obvious. Similar considerations apply to claims 4 and 5, *mutatis mutandis*. The remaining dependent claims 7-17 do not seem to contain further features which are not already disclosed or rendered obvious by the cited documents.